

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF MISSOURI  
CENTRAL DIVISION**

<b>EARL RINGO, et al.,</b>	)	
	)	
<b>Plaintiffs,</b>	)	
	)	
<b>vs.</b>	)	<b>No. 09-4095-CV-C-NKL</b>
	)	
<b>GEORGE A. LOMBARDI, et al.,</b>	)	
	)	
<b>Defendants.</b>	)	

**Plaintiffs' Reply to Defendants' Supplemental Brief  
Concerning Declaratory Judgment Actions**

Defendants argue that Plaintiffs cannot seek a declaratory judgment because they cannot sue for damages or an injunction under the Food, Drug and Cosmetics Act and the Controlled Substances Act. Defendants make a number of different arguments, but they are all variations on this theme—a theme that is disproven by the Declaratory Judgment Act’s allowance for declaratory relief “whether or not further relief is *or could be* sought.”<sup>1</sup>

**1. Injunctive or monetary remedies need not be available in order for Plaintiffs to have Article III standing in this declaratory judgment action.**

Just as in the motion to dismiss, Defendants exaggerate the requirement of “redressability” or “effective relief.” This time, Defendants belittle the “dubious proposition that parties may use a declaratory judgment action without having any other remedy available.”<sup>2</sup> But this supposedly “dubious” proposition comes not from Plaintiffs, but from the Declaratory Judgment Act itself. The Act allows a federal court to “declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.”<sup>3</sup> Defendants

---

<sup>1</sup>28 U.S.C. § 2201(a) (emphasis added).

<sup>2</sup>Doc. 56, at 6.

<sup>3</sup>28 U.S.C. § 2201(a).

essentially argue that Plaintiffs cannot truly be an “interested party,” because Plaintiffs can’t seek coercive relief. That position cannot possibly be correct, unless the Declaratory Judgment Act is itself unconstitutional for recognizing that non-coercing parties may bring cognizable cases. For the same reason, Defendants are mistaken in arguing that a party who can seek only declaratory relief cannot secure the “effective” relief that Article III requires. Again, if Defendants were correct, then the Declaratory Judgment Act would be unconstitutional for permitting suits that seek declaratory relief alone.

Equally untenable is Defendants’ attempt to distinguish *Franklin v. Massachusetts*,<sup>4</sup> *Powell v. McCormack*,<sup>5</sup> and *Steffel v. Thompson*.<sup>6</sup> Defendants insist that the plaintiffs in all three cases were able to seek at least some sort of non-declaratory relief, and thus, the ability to do so is somehow required for a plaintiff to have standing. Yet, none of these cases discuss such a requirement, and none rely on the availability of such relief in holding that the plaintiff could seek a declaratory judgment.

In *Franklin*, for example, the Court’s finding of standing did not depend on the plaintiffs’ ability to seek an injunction against the Secretary of Commerce.<sup>7</sup> If the availability of an injunction were at all relevant to the plaintiffs’ ability to seek the “effective” remedy of a declaratory judgment, then the Court would have said so. Instead, a declaratory judgment was sufficiently effective because the Court believed that the Secretary and the President would abide by a definitive statement of the law, “even though they would not be directly bound by such a

---

<sup>4</sup>505 U.S. 788 (1992).

<sup>5</sup>395 U.S. 486 (1969).

<sup>6</sup>415 U.S. 452 (1974).

<sup>7</sup>*Franklin*, 505 U.S. at 802.

determination.”<sup>8</sup> The other “offensive” cases in Plaintiffs’ supplemental brief are similar. Thus, prospective bacon eaters were allowed to seek a declaration that nitrites are a dangerous food additive, and without the slightest discussion of injunctive relief or its availability.<sup>9</sup>

Defendants next recycle their argument that “effective” relief in this case is “speculative” because the Court cannot force Defendants to change their method of execution.<sup>10</sup> But we need not speculate that Defendants will obey the law, because Missouri law presumes that public officials will do so.<sup>11</sup> At the very least, Plaintiffs are entitled to conduct discovery on the issue, and to ascertain whether the State’s executioners would abide by a declaration that their proposed conduct is a federal crime. Without discovery, it should not be assumed that Defendants will persist in their illegalities, or that they would necessarily remedy them through a “mere . . . piece of paper” and nothing more.<sup>12</sup> A law-abiding physician, for example, might decline to issue a prescription for a controlled substance that hasn’t been approved as an anesthetic in executions, much less when being administered by a nurse or EMT who is not licensed to administer it. Rather than resolving the case based on defense counsels’ say-so alone, the proper course is to allow discovery and factual development.

---

<sup>8</sup>*Id.* at 803.

<sup>9</sup>*Public Citizen v. Foreman*, 631 F.2d 969, 974 n.12 (D.C. Cir. 1980).

<sup>10</sup>Doc. 56, at 8-9.

<sup>11</sup>*Dittmeier v. Missouri Real Estate Commission*, 316 S.W.2d 1, 5 (Mo. 1958)

<sup>12</sup>Doc. 56, at 4 n.3

**2. Plaintiffs have “prudential” standing because they are within the “zone of interests” of the statutes they invoke, regardless of whether they can enforce those statutes by seeking prosecution, damages, or an injunction.**

Contrary to Defendants’ filing, “prudential” standing to seek declaratory relief depends not on whether a party may also seek coercive relief, but rather, whether the plaintiff is “arguably within the zone of interests to be protected or regulated by the statute or constitutional guarantee in question.”<sup>13</sup> The test is “not especially demanding.”<sup>14</sup> It specifically does *not* require a congressional intent “to benefit the would-be plaintiff,”<sup>15</sup> such as an express authorization to seek coercive relief or damages. The test is met when the interests of the declaratory plaintiff are consistent or “sufficiently congruent” with the underlying purpose of the law invoked.<sup>16</sup> In *American Nurses Association v. Leavitt*,<sup>17</sup> for example, a group of nurses permissibly sought a declaration that the Secretary of Health and Human Services violated the Medicare Act by allowing a private entity to ensure that hospitals were adequately staffed with nurses. Nurses, of course, are not the intended beneficiaries of the Medicare Act. The court nevertheless reasoned that understaffing of nurses could impair the quality of care delivered to Medicare’s beneficiaries. Therefore, the interests of the nurses’ group were consistent with those of Medicare patients.<sup>18</sup>

---

<sup>13</sup>*Canadian Lumber Trade Alliance v. United States*, 517 F.3d 1319, 1335 (Fed. Cir. 2008); *American Nurses Ass’n v. Leavitt*, 593 F. Supp. 2d 126, 133-34 (D.D.C. 2009), quoting *Elk Grove Unified School District v. Newdow*, 542 U.S. 1, 12 (2004).

<sup>14</sup>*American Nurses Ass’n*, 593 F. Supp. 2d at 134.

<sup>15</sup>*Id.*, *National Credit Union Admin. v. First Nat’l Bank & Trust Co.*, 522 U.S. 479, 489 (1998).

<sup>16</sup>*American Nurses Ass’n*, 593 F. Supp. 2d at 134, quoting *Citizens Exposing Truth about Casinos v. Kempthorne*, 492 F.3d 460, 464 (D.C. Cir.2007).

<sup>17</sup>593 F. Supp. 2d 126 (D.D.C. 2009).

<sup>18</sup>*Id.* at 134.

Similar reasoning allows Plaintiffs to seek declaratory relief here. A central purpose of the FDCA is to ensure that a “drug” be “safe and effective for its intended use.”<sup>19</sup> Sodium thiopental is administered in lethal injections to ensure that death-sentenced inmates do not suffer excruciating pain during execution.<sup>20</sup> That purpose is advanced by requirements of the FDCA and the CSA that controlled substances be prescribed by for “legitimate medical purposes” and by medical practitioners who are licensed to administer them<sup>21</sup>— in contrast to the DOC’s execution protocol, which allows the drugs to be administered by a nurse or emergency medical tech,<sup>22</sup> and without a lawful prescription and the sound medical judgment it entails. Plaintiffs’ suit, then, strikes at “*the* core objective of the FDCA.”<sup>23</sup>

Defendants nevertheless insist that declaratory judgment actions are not intended to be maintained by parties who cannot seek other relief. Because plaintiffs cannot privately “enforce” the FDCA or the CSA, the argument goes, Plaintiffs are intending to insert themselves between the only actual “parties” with actual “rights,” that is, the State of Missouri and the federal government.<sup>24</sup> But the existence of an otherwise enforceable “right” is not the test for whether declaratory relief is available. Otherwise, the Declaratory Judgment Act would not expressly

---

<sup>19</sup>*FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000); *United States v. Lane Labs-USA*, 324 F. Supp. 2d 547, 563-64 (D.N.J. 2004); 21 U.S.C. § 393(b)(2).

<sup>20</sup>*Clemons v. Crawford*, 585 F.3d 1119, 1125-27 (8th Cir. 2009); *Taylor v. Crawford*, 487 F.3d 1072, 1083-84 (8th Cir. 2007).

<sup>21</sup>21 U.S.C. 353(b)(1); 21 U.S.C. § 829(b) (Schedule III and IV controlled substances); 21 C.F.R. § 1306.04(a).

<sup>22</sup>*Clemons*, 585 F.3d at 1124.

<sup>23</sup>*Lane Labs*, 324 F. Supp. 2d at 563 (emphasis added).

<sup>24</sup>Doc. 56, at 4-5.

allow declaratory suits “whether or not further relief is or could be sought.”<sup>25</sup>

Equally misguided is Defendants’ reliance on an abrogated patent-law case for the proposition that a declaratory judgment suit must be brought by a party “at legal risk” from some “unresolved dispute.”<sup>26</sup> The case cited is no longer good law for the proposition urged, which the Supreme Court rejected when it held that a declaratory action does not require a “reasonable apprehension of suit.”<sup>27</sup> The Federal Circuit has since clarified that the fear of suit is merely one way, among others, that a declaratory plaintiff may establish Article III standing.<sup>28</sup> But no authority remotely suggests such a requirement for “prudential” or any other kind of standing.

---

<sup>25</sup>28 U.S.C. § 2201(a).

<sup>26</sup>Doc. 56, at 2, citing *Microchip Technology v. Chamberlain Group*, 441 F.3d 936 (Fed. Cir. 2006).

<sup>27</sup>*MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 132 n.11 (2007); see also *Argonide Corp. v. In-Tec Water Products*, No. 6:09-cv-852-Orl-28DAB, 2009 WL 4667398, at \*2 (M.D. Fla. Dec. 3, 2009) (stating that *Microchip Technology* does not survive *MedImmune*).

<sup>28</sup>*Prasco, LLC v. Medicis Pharmaceutical Corp.*, 537 F.3d 1329, 1336 (Fed. Cir.2008).

WHEREFORE, Plaintiffs respectfully renew their request that the Court deny the amended motion to dismiss.

Respectfully submitted,

/s/ Joseph W. Luby

Joseph W. Luby, Mo. Bar 48951  
Public Interest Litigation Clinic  
6155 Oak Street, Suite C  
Kansas City, MO 64113  
816-363-2795 • FAX 816-363-2799  
*Counsel for Plaintiff Winfield*

David Barron, Ky. Bar 90269  
100 Fair Oaks Lane, Suite 301  
Frankfort, KY 40601  
502-564-3948 • FAX -502-564-3949  
*Counsel for all Plaintiffs*

John William Simon, Mo. Bar 34535  
Constitutional Advocacy, L.L.C.  
2683 South Big Bend Blvd. #12  
St. Louis, MO 63143-2100  
314-604-6982 • FAX 314-754-2605  
*Counsel for Plaintiffs Bucklew and Middleton*

Cheryl Ann Pilate, Mo. Bar 42266  
Rebecca L. Kurz, Mo. Bar 40451  
Morgan Pilate LLC  
142 North Cherry  
Olathe, KS 66061  
913-829-6336 • FAX 913-829-6446  
*Counsel for Plaintiffs Bucklew, Middleton, and Ringo*

### **CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the foregoing was forwarded for transmission via Electronic Case Filing (ECF) this 14th day of December, 2009, to Andrew W. Hassell, Michael J. Spillane, Stephen D. Hawke, and Cheryl A. Schuetze, Office of the Attorney General, P.O. Box 899, Jefferson City, Missouri 65101.

/s/ Joseph W. Luby  
Joseph W. Luby

*Counsel for Plaintiff John E. Winfield*